510(k) Summary

Introduction

This summary is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Applicant

Mammendorfer Institut für Physik und Medizin GmbH
Oskar-von-Miller-Strasse 6
82291 Mammendorf, Germany

510(k) Correspondent

Robert N. Clark, President and Senior Consultant
Medical Device Regulatory Advisors
13605 West 7th Ave., Golden, CO USA
Tel: 303-234-9412 / Fax: 303-234-9413

Date Prepared

July 20, 2005

Trade Name of Device

Tesla Guard®

Common Name of Device

Patient Monitor

Classification Name

Monitor, Physiological, Patient (without arrhythmia detector or alarms)

510(k) Classification

21CFR§870.2300 / Class II
Product Code: MWI

Device Description and Intended Use

The Tesla Guard® design allows examination of intensive care patients while in an MRI-scanner. The Tesla Guard® construction, fiber optic finger probe, and additional shielding make it possible to use the device within the magnetic and RF fields of the MRI examination room. During use, the unit must be positioned in a way that the maximum field strength is not higher than 20 mT, and the distance to the magnet core is at least 1.5m.

Predicate Devices

Infinity Gamma XL manufactured by Dräger Medical Systems Inc. (K033600, K030313, K017016, K990563, K983632)

Safety & Effectiveness

Safety Testing

The Tesla Guard complies with the Safety Testing requirements of EN 60601-1 (IEC 601-1).

EMC Compliance

The Tesla Guard complies with the EMC requirements of standard EN 60601-1-2.

Biocompatibility

The patient contact portions of the Tesla Guard fiber optic finger probe comply with the biocompatibility requirements of standard ISO 10993-1.

Verification and Validation

Testing was completed to determine the influence of the Tesla Guard on the MRI system, and the influence of the MRI system on the Tesla Guard®.

Function and accuracy of the Tesla Guard was tested in both normal environment (Non MRI) and in MRI environment.

Laboratory Testing

Laboratory testing using human subjects was conducted to validate the functional and accuracy specifications of the pulse oximeter fiberoptic sensors, and to demonstrate equivalency to the predicate device.

Risk Management

This device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program.

The user must be qualified in MRI procedures, and must be familiar with all labeling and instructions for use associated with the device.

Mammendorfer Institut für Physik und Medizin GmbH believes that the Tesla Guard® is safe and effective when used as instructed by knowledgeable and trained personnel, and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 2006

Mammendorfer Institute for Physics and
Medicine GmbH
c/o Mr. Robert Clark
President
Medical Device Regulatory Advisors
13605 West 7th Ave.
Golden, CO 80401-4604

Re: K052119
Trade Name: Tesla Guard ®
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: Novewmber29, 2005
Received: December 01, 2005

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052119

Device Name: *Tesla*^{Guard} ®

Indications For Use:

The *Tesla*^{Guard} ® Patient Monitor is capable of monitoring:

- SpO2 (Arterial Oxygen Saturation)
- ECG (3-Lead)
- IBP (Invasive Blood Pressure)
- NIBP (Non-invasive Blood Pressure)

This device will produce visual and audible alarms if any of these parameters vary beyond preset limits.

The device is intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated based upon their professional assessment of the patient's medical condition.

The device is intended for use in the Adult, Pediatric and Neonatal populations.

MRI Compatibility Statement:

The *Tesla*^{Guard} ® Patient Monitor is designed for use in an MRI-environment at a maximum magnetic field strength of 20mT.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052119